IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE WELLBUTRIN SR/ZYBAN ANTITRUST LITIGATION	)	**Master File No. 02-CV-4398**
THIS DOCUMENT RELATES TO: ALL ACTIONS	)	

MEMORANDUM AND ORDER

Kauffman, J. **July , 2003**

Plaintiffs bring this putative class action on behalf of all indirect purchasers of Wellbutrin SR and Zyban ("Wellbutrin SR")[1] alleging that Defendants GlaxoSmithKline plc and SmithKline Beecham Corporation ("Defendants") engaged in a series of anticompetitive and unlawful actions that extended their exclusivity of the sale of Wellbutrin SR. Plaintiffs assert that they are entitled to injunctive relief under Section 16 of the Clayton Act as a result of Defendants' monopolization and attempted monopolization in violation of Section 2 of the Sherman Act (Count I). Plaintiffs also assert that Defendants' conduct supports causes of action under state law for monopolization (Count II), unfair and deceptive trade practices (Count III), and unjust enrichment (Count IV). Now before the Court is Defendants' Motion to Dismiss the Complaint. For the following reasons, the Court will deny the Motion.

[1] Wellbutrin SR and Zyban have the same active ingredient, bupropion hydrochloride. (Consolidated Class Action Complaint ("Complaint") ¶¶ 2-3.) However, although both Wellbutrin SR and Zyban have the same chemical composition and are covered by the same patent, they are marketed for different treatments – antidepression and smoking cessation, respectively. (Complaint ¶ 2.) Accordingly, manufacturers seeking to sell a sustained release formula of bupropion hydrochloride must file Abbreviated New Drug Applications with the FDA requesting approval to sell generic versions of Wellbutrin SR & Zyban. (Complaint ¶ 2.)

I. Background

A. Statutory Framework for Pioneer and Generic Drug Approval

Ordinarily, a company wishing to market a new drug must seek the approval of the United States Food & Drug Administration ("FDA") by completing a New Drug Application ("NDA"). However, after enactment of the Drug Price Competition and Patent Term Restoration Act in 1984 (the "Hatch-Waxman Act" or the "Act"), a generic pharmaceutical manufacturer seeking FDA approval to market a drug no longer needs to complete a full NDA. Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, codified at 21 U.S.C. § 355(j). Instead, under 21 U.S.C. § 355(j), a generic company may file an Abbreviated New Drug Application ("ANDA") which relies on the FDA's previous findings of safety and efficacy. The applicant must include in the ANDA a certification that the proposed generic drug would not infringe existing valid patents by its manufacture, use, or sale. 21 U.S.C. § 355(j)(2)(A)(vii). If the generic applicant claims that a relevant patent is invalid or will not be infringed by its product, it must so certify to the FDA, and notify the patent-holder. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (commonly known as "paragraph IV certification"); 21 U.S.C. § 355(j)(2)(B)(i). The patent-holder then has forty-five days within which to bring a patent infringement suit against the applicant. If the patent-holder brings such a suit, the FDA's approval of the ANDA is automatically delayed for thirty months or until the patent suit is declared invalid or not infringed ("30-month stay"). 21 U.S.C. § 355(j)(5)(B)(iii).

Additionally, the Act provides a significant incentive to generic-drug manufacturers who file the first ANDA ("first filer"). The Act grants the first filer a 180-day period of market exclusivity before subsequent ANDA filers can enter the market. 21 U.S.C. § 355(j)(5)(B)(iv).

The 180-day period begins to run when the first filer commercially markets the generic drug or when the court declares the existing patent invalid. Id.

B. Facts of the Case

Taking all well-pleaded allegations as true, the relevant facts are as follows.[2] The patent for bupropion hydrochloride, the active ingredient in Wellbutrin SR, expired over ten years ago. (Complaint ¶¶ 48 -51.) However, Defendants currently have a monopoly on the market for bupropion hydrochloride because they have a separate unexpired patent on a sustained-release formulation of the drug which eliminates the need to take the medication three or four times a day. (Complaint ¶¶ 52, 66.) The sustained-release formulation is made possible by combining

[2] In addition to the facts alleged in the Complaint, Defendants ask the Court to take judicial notice of a published report of a federal administrative agency (the FDA), posted on the official FDA website, which makes clear that Andrx, the first generic drug manufacturer to file an ANDA for Wellbutrin SR, has not yet received FDA approval. See FDA's Center for Drug Evaluation and Research Listing of New & Generic Drug Approvals, <http://www.fda.gov/cder/approval/b.htm>.

Generally, when deciding a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the Court may look only to the facts alleged in the complaint and its attachments. Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1250, 1261 (3d Cir. 1994). However, matters of public record may also be considered without converting the motion to dismiss into a motion for summary judgment. Pension Ben. Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). Courts have defined a public record to include published reports of administrative bodies. See id. at 1197. The fact that an agency report is "published" on the world wide web does not affect the Court's ability to take judicial notice of the contents of that report. See McLaughlin v. Volkswagen of Am., Inc., 2000 WL 1793071, at *1 (E.D. Pa. 2000) (taking judicial notice of National Highway Traffic Safety Administration's website description of vehicle recall in considering a 12(b)(1) motion); see also In re Agribiotech Sec. Litig., 2000 U.S. Dist. LEXIS 5643, at *4-5 (D. Nev. 2000) (taking judicial notice of official government documents available on the world wide web). Accordingly, the Court will take judicial notice of the FDA's Center for Drug Evaluation and Research Listing of New & Generic Drug Approvals 1998 - 2003 and its listing of bupropion hydrochloride which is available at <http://www.fda.gov/cder/approval/b.htm>.

buproprion hydrochloride with the excipient hydroxypropyl methylcellulose ("HPMC").[3] (Complaint ¶ 55.) It is this combination of buproprion hydrochloride and HPMC which is covered by Patent No. 5,427,798 (the "'798 Patent") and marketed as Wellbutrin SR. (Complaint ¶¶ 55, 66, 67.)

Beginning in August 1999, several generic-drug manufacturers, including Andrx Pharmaceuticals ("Andrx"), Eon Labs, Impax Laboratories, Excel Pharmaceuticals and Watson Laboratories sought approval to market generic versions of Wellbutrin SR.[4] (Complaint ¶ 71-73.) In each case, the generic manufacturer's ANDA requested approval of a buproprion hydrochloride sustained release tablet that did not use HPMC as a control release agent and therefore did not infringe upon any valid patent. (Complaint ¶¶ 71-74.) However, even though Defendants knew that the '798 Patent was not infringed, they filed frivolous patent infringement actions against each generic-drug manufacturer within the forty-five day period, thus triggering the 30-month stay.[5] (Complaint ¶¶ 71-116.)

Plaintiffs subsequently brought this lawsuit, claiming that but for Defendants' illegal conduct, a generic competitor could have begun marketing a generic version of Wellbutrin SR as

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[3] An excipient is an inert ingredient or substance added to a prescription to give the desired consistency or form.

[4] Andrx submitted its ANDA with the FDA seeking approval to market a generic version of Wellbutrin SR in August of 1999. (Complaint ¶ 75). Accordingly, Andrx is considered the "first filer" under the Hatch-Waxman Act and is entitled to the 180-day exclusivity period.

[5] Plaintiffs state that Defendants' patent lawsuits were frivolous because the patent specifications and patent prosecution history make clear that the '798 Patent is a narrow patent claiming a specific form of extended release tablet of bupropion which incorporates the high viscosity, high polymer weight form of the excipient HPMC as a control release agent. (Complaint at ¶ 68.) For the purposes of this Motion, Defendants concede that the five Patent lawsuits were frivolous. (Oral Argument Transcript at 20-21, 100.)

early as September 15, 1999. (Complaint ¶¶1, 3, 5, 6, 117, 118, 122, 128, 158, 161.) Plaintiffs further state that as a direct and proximate result of Defendants' conduct, Plaintiffs and putative class members were deprived of the benefits of competition and were forced to pay inflated prices for Wellbutrin SR.

The sole basis of Defendants' Motion to Dismiss is that Plaintiffs have not and cannot allege that Defendants' actions caused Plaintiffs' injury.

II. Legal Standard

When deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court may look only to the facts alleged in the complaint and its attachments. Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1250, 1261 (3d Cir. 1994); but see Pension Ben. Guar. Corp., 998 F.2d at 1196.[6] The Court must accept as true all well-pleaded allegations in the complaint and view them in the light most favorable to the plaintiff. Angelastro v. Prudential-Bache Sec., Inc., 764 F.2d 939, 944 (3d Cir. 1985); Markowitz v. Northeast Land Co., 906 F.2d 100, 103 (3d. Cir. 1990). A Rule 12(b)(6) motion will be granted only if "no relief could be granted under any set of facts consistent with the allegations of the complaint." Trump Hotels and Casino Resorts, Inc. v. Mirage Resorts, Inc.,140 F.3d 478, 483 (3d Cir. 1998); see also H.J. Inc. v. Northwestern Bell Tel. Co., 492 U.S. 229, 249-50 (1989); Ransom v. Marrazzo, 848 F.2d 398, 401 (3d Cir. 1988).

III. Analysis

Defendants argue that even if they had filed frivolous lawsuits for the purpose of triggering the 30-month stay, Plaintiffs' Complaint must be dismissed because there is no causal

[6] See note 2 supra.

connection between this illegal conduct and the alleged injury, the unavailability of generic Wellbutrin SR.

A plaintiff stating a cause of action for injunctive relief under Section 16 of the Clayton Act must also allege that the claimed loss or threat of loss was caused by the alleged antitrust violation.[7] City of Pittsburgh v. West Penn. Power Co., 147 F.3d 256, 265-67 (3d Cir. 1998). 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 338 at 316-321 (2d ed. 2000). Although an allegation of causation is essential, the Supreme Court has declared that a plaintiff need only show that a violation is a "material cause" of the claimed injury. See Zenith Radio Corp. v. Hazeltine Research, 395 U.S. 100, 114 n.9 (1969); see also 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP ¶ 338a at 317 ("[T]o require proof that the illegal conduct was the *exclusive* cause of the plaintiff's injury would effectively deny private remedies, because multiple causes always affect everyone.") On occasion, however, an independent cause fully accounts for the plaintiff's alleged injury and breaks the causal connection between the alleged antitrust violation and the plaintiff's injury. 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP ¶ 338b at 320; City of Pittsburgh, 147 F.3d at 268-69 (3d Cir. 1999) (finding that there was no causal connection between plaintiff's injuries and the alleged harm due to an intervening regulatory scheme). This may occur even though a defendant has committed a per se antitrust violation.

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[7] Section 16 of the Clayton Act ("Section 16") states that a person "threatened [with] loss or damage by a violation of the antitrust laws" can seek injunctive relief. The Clayton Act includes the Sherman Act as one of the "antitrust laws". To allege the offense of actual monopoly under Section 2 of the Sherman Act, a plaintiff must claim: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." See United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966).

See Atlantic Richfield Co. v. USA Petroleum, 495 U.S. 328, 341-45 (1990) (finding that even when a per se violation of the antitrust laws occurs, a plaintiff is still required to demonstrate antitrust injury as an element of a successful claim). When a defendant relies upon the existence of an independent cause, however, such cause "must be examined closely to make sure that it is the independent cause, rather than the illegal antitrust action, that gives rise to the plaintiff's injury." 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP ¶ 338b at 321.

Here, Defendants argue that Plaintiffs' injuries flow not from the alleged antitrust violation, but rather from an independent cause -- the requirements of the FDA and the Hatch-Waxman Act. Defendants contend that the superceding cause for Andrx's failure to enter the market is the company's inability to obtain FDA approval. Defendants assert that even if they had filed frivolous lawsuits for the purpose of extending their monopoly, their actions are not responsible for Andrx's lack of entry because the 30-month stay has expired and Andrx has still failed to secure FDA approval, a prerequisite for entry into the market. See Andrx Pharmaceuticals, Inc. v. Biovail Corp. Intl., 256 F.3d 799, 807 (2001) ("In the pharmaceutical industry, FDA approval is a prerequisite to enter *any* drug market."). Defendants further argue that Andrx's failure to obtain FDA approval has prevented other generic companies from coming to market because under the Hatch-Waxman Act, no generic applicants can obtain final FDA approval until the first filer's 180-day period of market exclusivity has elapsed.

Defendants' ability to pose a plausible and legally permissible version of events that explains why generic manufacturers of Wellbutrin SR have not yet entered the market does not compel this Court to grant their Motion. Rather, because this is a motion to dismiss, the Court must draw all reasonable inferences in favor of Plaintiffs. Here, Plaintiffs have alleged that

Defendants filed frivolous lawsuits for the purpose of delaying market entry of generic Wellbutrin SR. (Complaint ¶ 5, 118). In addition to the triggering of the 30-month stay, the filing of these lawsuits initiated burdensome patent litigation, which Plaintiffs allege created and continues to serve as an obstacle to the generic-drug companies' entry into the market.[8]

In the face of these patent lawsuits, it is reasonable to infer that Andrx and the other generic companies directed resources away from FDA approval and toward the defense of the infringement actions and, furthermore, that this reallocation of funds resulted in a delay of FDA approval. See Bristol-Myers Squibb Co. v. Ven Venue Laboratories, 90 F. Supp. 2d 540, 545 (D.N.J. 2000) (noting that "because FDA approval would be meaningless in the absence of a favorable court ruling on infringement or validity, the generic companies are better served to direct their resources toward defense of the infringement action"). Based on this inference, one could conclude that the intervening cause alleged by Defendants, the failure of Andrx to obtain FDA approval, was itself caused by Defendants' filing of the allegedly frivolous lawsuits. Thus, although it is possible that the frivolous lawsuits did not cause Plaintiffs' harm due to the lack of FDA approval, it is also possible that these lawsuits generated circumstances which are responsible for the lack of FDA approval itself. Accordingly, because Plaintiffs may be able to prove that the allegedly frivolous lawsuits "materially caused" their alleged injuries, the Court will deny Defendants' Motion.

IV. Conclusion

[8] Defendants argue that any obstacles imposed by these patent lawsuits cannot be considered "burdensome" as a matter of law if the suits themselves were objectively baseless. This Court disagrees because all litigation, particularly complex federal litigation involving patent issues, imposes some burden on the parties involved regardless of the merits of the claims.

For the foregoing reasons, the Court will deny Defendants' Motion to Dismiss Plaintiffs' Complaint. An appropriate Order follows.

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ORDER

AND NOW, this _____ day of July, 2003, after oral argument and upon consideration of Defendants' Motion to Dismiss (docket no. 13), Plaintiffs' Response (docket no. 17), Defendants' Reply thereto (docket no. 19), Defendants' Supplemental Memorandum (docket nos. 25, 27), and Plaintiffs' Supplemental Memorandum (docket no. 28), it is **ORDERED** that Defendants' Motion to Dismiss is **DENIED** for the reasons stated in the accompanying Memorandum.

BY THE COURT:

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BRUCE W. KAUFFMAN, J.